# EXHIBIT 10

# Operative Environment

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## Question 1: Do numbers of bacteria arriving in the surgical wound correlate directly with the probability of surgical site infection (SSI)?

### Consensus

We recognize that the probability of SSI correlates directly with the quantity of bacteria that reach the wound. Accordingly we support strategies to lower particulate and bacterial counts at surgical wounds.

### Delegate Vote

Agree: 97%, Disagree: 2%, Abstain: 1% (Strong Consensus)

### Justification

Postoperative SSIs are believed to occur via bacterial inoculation at the time of surgery or as a result of bacterial contamination of the wound via open pathways to the deep tissue layers.[1–3] The probability of SSI is reflected by interaction of parameters that can be categorized into three major groups.[2] The first group consists of factors related to the ability of bacteria to cause infection and include initial inoculation load and genetically determined virulence factors that are required for adherence, reproduction, toxin production, and bypassing host defense mechanisms. The second group involves those factors related to the defense capacity of the host including local and systemic defense mechanisms. The last group contains environmental determinants of exposure such as size, time, and location of the surgical wound that can provide an opportunity for the bacteria to enter the surgical wound, overcome the local defense system, sustain their presence, and replicate and initiate local as well as systemic inflammatory reactions of the host.

The use of iodine impregnated skin incise drapes shows decreased skin bacterial counts but no correlation has been established with SSI. However, no recommendations regarding the use of skin barriers can be made (see this Workgroup, Question 27).

## Question 2: Do numbers of bacteria in the operating room (OR) environment correlate directly with the probability of SSI?

### Consensus

We recognize that airborne particulate bacteria are a major source of contamination in the OR environment and that bacteria shed by personnel are the predominant source of these particles. The focus of our recommendations is to reduce the volume of bacteria in the OR with particular attention to airborne particles.

### Delegate Vote

Agree: 93%, Disagree: 5%, Abstain: 2% (Strong Consensus)

### Justification

Air is a potential source of contamination in the OR.[2,4] Studies have demonstrated that the number of airborne bacteria around the wound is correlated to the incidence of periprosthetic joint infection (PJI).[1] It has been suggested that if it was possible to measure accurately the number of bacteria present in the wound it should constitute the most precise predictor of subsequent infection.[5] Bacteria can be considered as part of the total mass of particulates in the air. Some studies have suggested that the airborne particulate count should be considered as potential surrogate for airborne microbial density.[6] Others have found a correlation between the number of particulates larger than 10 μm with the density of viable bacteria at the site of surgery (measured by colony forming units).[7] It has been suggested that monitoring particulate count be used as a real-time proxy for increased risk of wound contamination or infection.[7] Persons in the OR are a major source of bacterial load and shed bacterial particulates. These particulates circulate through the OR via air currents. Movements of personnel and objects (including OR equipment) and opening and closing doors can generate significantly marked air currents and increase the probability of bacteria being deposited in the surgical site.[3,8]

## Question 3: Should the OR in which an elective arthroplasty is performed be fitted with laminar air flow (LAF)?

### Consensus

We believe that arthroplasty surgery may be performed in operating theaters without laminar flow. Laminar flow rooms and other strategies that may reduce particulates in operating rooms would be expected to reduce particulate load. Studies have not shown lower SSI in laminar flow rooms and some

cases are associated with increased rates of SSI. These are complex technologies that must function in strict adherence to maintenance protocols. We recommend further investigation in this field.

#### Delegate Vote

Agree: 85%, Disagree: 7%, Abstain: 8% (Strong Consensus)

#### Justification

The most cited studies supporting the use of LAF were conducted in the 1970s and 1980s by Charnley[9] and Lidwell et al.[10] However, several recent studies have shown no clear benefit of LAF in reducing the incidence of deep SSI.[11–14] Breier et al.[11] conducted a nationwide study in Germany, controlling for confounding factors with multivariate analysis, and found no independent effect of LAF on SSI rates, even when considering LAF rooms with large ceiling sizes (at least $3.2\,\mathrm{m} \times 3.2\,\mathrm{m}$).

A recent study by Hooper et al.[13] that was based on the New Zealand joint registry evaluated the subject on a wide basis. The authors analyzed 51,485 total hip arthroplasties (THA) and 36,826 total knee arthroplasties (TKA) and revealed increased early infection rates with laminar flow use, especially for THA patients. This increase was found to be independent of patient characteristics, operative time, surgeon, or institution. Unfortunately, except for the study performed by Salvati et al. in which horizontal LAF was found to increase the risk of PJI in TKA, other studies, including those supporting the use of LAF,[10] those opposing its use,[13] and those with indifferent results,[15–17] did not conduct any sub-analysis to distinguish influence of different types of LAF on PJI.

### Question 4: Is there enough evidence to enforce the universal use of body exhaust suits during total joint arthroplasty (TJA)?

#### Consensus

There is currently no conclusive evidence to support the routine use of space suits in performing TJA.

#### Delegate Vote

Agree: 84%, Disagree: 11%, Abstain: 5% (Strong Consensus)

#### Justification

Similar to the situation with laminar flow, the use of space suits during TJA has become a subject of controversy. A recent study by Miner et al.[14] showed no benefit in the use of body exhaust suits and a study by Hooper et al.[13] evaluating the use of a space suit and its effect on early infection rates identified an increased rate of early infection with the use of space suits both in conventional and in laminar flow theaters. However, there is some suggestion that space suits should be worn in laminar flow-fitted rooms to prevent contamination.[18,19]

### Question 5: What strategies should be implemented regarding OR traffic?

#### Consensus

We recommend that OR traffic should be kept to a minimum.

#### Delegate Vote

Agree: 100%, Disagree: 0%, Abstain: 0% (Unanimous Consensus)

#### Justification

Personnel are the major source of air contamination in the OR, both by traffic that creates turbulence and contaminates ultraclean air and by bacterial shedding. Ritter et al.[17] showed that bacterial counts in OR air increased 34-fold in an operating room with five people compared to an empty room. Keeping the OR door open also significantly increased bacterial air contamination of the room in the same study. Andersson et al.[15] showed a positive correlation between traffic flow rates and air bacterial counts in orthopedic procedures. They also identified a direct correlation between the number of people present in the OR and bacterial counts. Quraishi et al.[20] further demonstrated a direct correlation between the activity level of OR personnel and bacterial fallout into the sterile field. Panahi et al.[21] observed door openings during primary and revision TJA cases. They identified 0.65 and 0.84 door openings per minute in primary and revision cases, respectively. The main personnel responsible for door openings were implant technical representatives and circulating nurses. Lynch et al.[22] showed an exponential relationship between the number of door openings and the number of personnel in the OR. In their series, information requests (an easily avoidable cause) was the reason for the majority of door openings. Multiple door openings can result in a drop in the pressure gradient requiring more air being pumped through LAF systems and therefore the high efficiency particulate air filters are consumed more quickly. It has been proposed by experts that OR personnel pass through a sub-sterile hallway every time they enter or leave the OR, although evidence regarding this practice is lacking. If preoperative templating is possible, available sizes of the implants should be in the OR at the start of the surgery.

### Question 6: Should operating lights be controlled with a foot pedal as opposed to reaching above eye level?

#### Consensus

We recommend a general awareness that light handles can be a source of contamination and to minimize handling of lights as much as possible. Other strategies for light control need to be developed in the future to minimize contamination.

#### Delegate Vote

Agree: 91%, Disagree: 4%, Abstain: 5% (Strong Consensus)

### Justification

Davis et al.[23] identified a 14.5% rate of contamination of sterile light handles during TJA cases. Hussein et al.[24] showed no evidence of contamination of the sterile light handle (autoclaved plastic or metallic) after 15 cases of primary TJA. However, we were unable to identify other studies in the literature addressing the risk of contamination of the surgeon's gown or of parts of the sterile field when compared with reaching up for light adjustment, or studies that looked at air disruptions secondary to the movement of the surgeon reaching above eye level.

## Question 7: Is there a role for ultraviolet (UV) light use in the prevention of infection after TJA?

### Consensus

We agree that UV light environments can lower infection rates, but recognize that this can pose a risk to OR personnel. We recognize that the benefit of UV might be the inhibition of operating traffic.

### Delegate Vote

Agree: 74%, Disagree: 13%, Abstain: 13% (Strong Consensus)

### Justification

Even though UV light use has been shown to significantly decrease the number of bacterial counts in the OR, as well as the occurrence of postoperative infection, its use is harmful for OR personnel and increases the risk of corneal injuries and skin cancer; as such, current guidelines from the Centers for Disease Control (CDC) recommend against the use of UV lights in the OR to prevent SSIs.[5,25–30]

## Question 8: Do UV decontamination/sterilization lights or portable units in unoccupied ORs (nights and weekends) make a difference in the sterility of the OR environment?

### Consensus

UV would be expected to lower bacterial load in ORs, but the technology has not been studied in this application. It might be considered an adjunct but not a replacement for conventional cleaning. There are potential risks to staff by UV technology inadvertently left on at the start of the work day.

### Delegate Vote

Agree: 84%, Disagree: 3%, Abstain: 13% (Strong Consensus)

### Justification

After a thorough literature search, we were unable to identify evidence to support or refute the use of UV light to keep the OR environment sterile outside operative times.

## Question 9: Should the patient and OR personnel wear a mask to avoid contamination of the OR air?

### Consensus

Despite the absence of conclusive studies that show a reduction in SSI when surgical masks are worn properly and uniformly by all staff, we believe there is reason to expect particulate airborne bacteria counts to be reduced by disciplined use of surgical masks. Until evidence appears that shows an advantage to NOT wearing a mask, we believe that it is in the interest of patient safety that all personnel wear surgical masks at all time that they are in the OR. There is insufficient evidence to support the use of masks by patients that outweighs the benefit of airway access.

### Delegate Vote

Agree: 85%, Disagree: 7%, Abstain: 8% (Strong Consensus)

### Justification

Several authors have questioned the utility of face masks worn by OR personnel in preventing air and wound contamination.[31–33] A study by Lipp and Edwards[32] included three randomized controlled trials (RCTs)with a total of 2,113 subjects and concluded that the use of face masks had no significant effect on surgical wound infections in patients undergoing clean surgery. Sellden et al.[34] decided to refrain from the use of face masks for unscrubbed personnel in the OR. A recent RCT by Webster et al.[35] showed that if none of the non-scrubbed OR personnel wore a face mask, there was no increase in the rate of SSIs. However, this study included non-orthopedic as well as orthopedic procedures and followed patients for only 6 weeks postoperatively. Furthermore, it was not clear if orthopedic procedures included implantation procedures. We were unable to identify studies looking specifically at face masks worn by the patient undergoing TJA or studies evaluating the benefit of this practice in reducing OR air contamination.

## Question 10: What garments are required for OR personnel?

### Consensus

We recommend that all personnel wear clean theater attire including a disposable head covering, when entering an OR. Garments worn outside of the hospital should not be worn during TJA.

### Delegate Vote

Agree: 98%, Disagree: 1%, Abstain: 1% (Strong Consensus)

### Justification

Some aspects of the appropriate attire for surgical personnel (such as surgical gowns and gloves) have been addressed in other sections. Controversy has been raised regarding the utility of surgical masks or

head coverings in the prevention of SSI based on inconsistent results from experimental and clinical investigations in the field of general surgery, gynecology, and cardiology (cardiac catheterization).[36–42] Nevertheless, as affirmed by CDC guidelines,[28] use of surgical masks by all OR personnel is an advantageous and harmless behavior that provides a mechanical obstacle for OR personnels' oro- and nasopharyngeal secretions. These secretions may contain bacterial particulates and all efforts should be made to decrease the risk of exposure of surgical wound to these particulates. Moreover, masks can also be beneficial in protecting the personnel from patients' blood or other bodily fluids.

## Question 11: What restrictions should be placed on the use of portable electronic devices (such as mobile phones, laptops, tablets, or music devices) in the OR?

### Consensus

We recognize that portable electronic devices may be contaminated with bacteria. We also recognize that increased levels of talking are associated with higher levels of bacteria in the OR environment. Accordingly we recommend that portable electronic device usage be limited to that which is necessary for patient care.

### Delegate Vote

Agree: 84%, Disagree: 14%, Abstain: 2% (Strong Consensus)

### Justification

Many studies have shown a high rate of contamination of cell phones and other portable electronic devices used in hospitals by healthcare workers, from 44% to 98%, with a high percentage of resistant strains, namely extended-spectrum β-lactamase-producing Gram-negative bacteria and methicillin-resistant *Staphylococcus aureus* (MRSA).[43–49] Ulger et al.[48] demonstrated that 52% of *S. aureus* strains isolated from cell phones were methicillin-resistant. Brady et al.[43] showed that cleaning mobile phones with an alcohol-based solution significantly reduced contamination of mobile phones, similar to what was previously observed by Singh et al.[50] for pagers and Hassoun et al.[51] for personal digital assistants. Thus, regular cleaning of portable electronic devices with alcohol is highly recommended, as efforts towards maintaining hand hygiene to prevent nosocomial infections, including SSI, may be compromised by the use of handheld electronic devices that act as reservoirs of pathogens. Limitation of portable electronic devices in the OR is also advised, although no evidence in the literature is able to link their use to an increased risk of SSI.

## Question 12: Does prolonged surgical time predispose to an increased risk of PJI?

### Consensus

We recognize that SSI rates increase directly with the duration of surgery. We recognize that some surgeries present a marked and inescapable level of complexity that will require more time. We recognize that minimizing the duration of surgery is an important goal and a cooperative effort on the base of the entire surgical team as well as the institution. We recommend that a coordinated effort be made to minimize the duration of surgery without technical compromise of the procedure.

### Delegate Vote

Agree: 96%, Disagree: 3%, Abstain: 1% (Strong Consensus)

### Justification

Numerous studies have linked increased operative time to the risk of infection after TJA with statistical significance.[52–65] Skramm et al. investigated the incidence of SSI following THA and TKA for fractures after the implementation of surveillance policies. When considering the risk factors for infection, the duration of surgery was the only significant independent factor in a logistic regression model, also taking into account age, American Society of Anesthesiologists' physical status score, and level of emergency.[61] The study by van Kasteren et al.[64] supported the use of duration of surgery more than the 75th percentile as a risk factor for PJI, as previously suggested by the National Noscomial Infections Surveillance risk index.[66] In a population-wide study based on the Danish national hip arthroplasty registry that included 80,756 cases of primary THA, surgical time was a significant independent risk factor for revision due to infection.[57] Similar results were reported in countries such as Norway and England.[60,62] Peersman et al.[58] suggested using operative times as a predictive risk factor for infection after TKA in a risk stratification model. In a systematic review of only observational studies that investigated deep SSI in THA and included more than 100 patients, Urquhart et al. found just two studies that examined operative time.[63] After merging data from these two studies, they reported duration of surgery as an independent risk factor for SSI. In addition, in a recent analysis of 56,216 primary TKAs, Namba et al. identified a 9% increase in the risk of deep SSI per 15 min-increment increase in operative time.[56]

Nevertheless, methodological concerns exist regarding the studies that support the role of operative time as a risk factor for PJI, including missing data,[9] failure to consider potential confounding factors,[57,58] and statistical considerations.[59–61] On the other hand, there are studies that failed to demonstrate such a correlation[67] or even found an opposite relationship.[68] Moreover, none of the previous studies considered the potential confounding role of repeat doses of antibiotic prophylaxis during prolonged procedures. Procedure duration may be an indicator of complexity of surgery (extensive surgical exposure and more severe tissue damage), surgical indication (previous procedures and indications other than osteoarthritis), inexperienced

surgical team, surgeon with slow pace, perioperative complications, inadequate optimal standardization program, or patient's preexisting medical conditions.[57,69,70] Perhaps staff education in how to operate efficiently and follow systematically defined steps might decrease the risk of SSI. It has also been demonstrated that procedures with a longer duration are at increased risk for revision due to aseptic failure.[62]

### Question 13: Should the scheduling of elective TJA be ordered so that clean cases are not preceded by known infected, dirty, or contaminated cases?

#### Consensus

We recognize the concern regarding risk of infection to a clean surgery following a contaminated surgery. We recognize that studies have not demonstrated increased infection rates in clean surgery performed subsequent to contaminated cases. We recommend thorough cleaning after contaminated surgery and before further surgery, as defined by local institutional standards.

#### Delegate Vote

Agree: 89%, Disagree: 8%, Abstain: 3% (Strong Consensus)

#### Justification

Although performing an infected arthroplasty procedure before non-infected procedures is theoretically risky for cross-contamination between procedures, there is inadequate evidence to support or oppose this practice. However, this policy may allow the hygiene staff a thorough clean down procedure at the end of the OR working day when there is no economical concern regarding the duration of time that might be required for a compliant OR disinfection.

A common practice in orthopedic surgery, especially in arthroplasty, is to organize the OR in a manner so that confirmed or suspicious cases of infection are operated on at the end of the OR session after clean procedures. Whether the practice of performing a clean arthroplasty procedure following an infected case increases the probability of infection or not has not been adequately studied. Microbiologic studies have demonstrated long-term survivorship of common nosocomial pathogens on inanimate surfaces.[71] This may support the theoretical risk of cross-contamination between procedures if there is no efficient preventive strategy for disinfection of these surfaces after every procedure. There are only two retrospective studies that have addressed this issue, but both had inadequate power and inconsistent conclusions.[72,73] Despite the lack of evidence, a sound practice consists of thoroughly addressing this potential factor of PJI, even though there is inadequate evidence for cross-contamination between procedures.

Abolghasemian et al.[72] evaluated 85 primary and revision cases performed after TJA resection for PJI and evaluated the risk of infection in those patients. After a minimum follow-up of 12 months, an increased rate of superficial or deep infections was not witnessed in this cohort when compared to 321 patients matched for demographic factors who did not undergo TJA after an infected TJA in the same OR. The one patient who developed a deep PJI in the study group had a different infecting organism than the one responsible for the PJI of the preceding surgical case. Cleaning the OR after an infected case did not differ from cleaning after an aseptic case. Namdari et al. undertook a similar endeavor when they evaluated the development of infection in 39 cases of primary TJA performed after dirty cases. They identified one case of PJI in this cohort when the causative infecting organism (*Propionibacterium acnes*) was the same as the one causing the infection in the preceding septic case. However, no advanced microbiological testing was performed to certify that both organisms were of identical strains.[73]

### Question 14: Does patient normothermia have an essential role in preventing infectious complications?

#### Consensus

We recognize the significance of patient normothermia and the data from non-orthopedic procedures. We support general recommendations from the general surgery literature and identify this as a field that requires further research.

#### Delegate Vote

Agree: 92%, Disagree: 1%, Abstain: 7% (Strong Consensus)

#### Justification

Kurz et al.[74] undertook an RCT of major colorectal surgery patients and demonstrated significant decrease in SSI rates in patients receiving warmed fluids and forced-air warming (FAW) blankets compared to patients who did not receive aggressive maintenance of normothermia. Melling et al.[75] conducted an RCT in non-orthopedic clean surgery and identified a significant role for patient warming in preventing SSI. A systematic protocol using FAW blankets or local warming protocols using a radiant heat dressing led to a significant decrease in SSI. No such RCT was identified specifically for TJA or orthopedic procedures in general.

### Question 15: Do FAW blankets increase the risk of SSI?

#### Consensus

We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.



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**Delegate Vote**
Agree: 89%, Disagree: 5%, Abstain: 6% (Strong Consensus)

**Justification**
Recent studies have raised concern about the possibility of bacterial air contamination by FAW devices. Some authors evaluated disruptions in airflow. McGovern et al.[76] conducted an experimental study where they found that FAW blankets lead to a disruption in the airflow at the surgical site under LAF conditions when compared to conductive fabric warmers in simulated THA and spine surgery. Legg et al.[77] found increased air particles above the surgical site when using FAW compared to radiant warming. On the contrary, Sessler et al.[78] did not identify any worsening in air quality with use of FAW under laminar flow conditions. Memarzadeh et al.[79] reported the results of a computational study conducted by the National Institutes of Health which showed negligible disruption of laminar flow by FAW.

Other authors have investigated the bacterial contamination of OR air. Moretti et al.[80] undertook air sampling in experimental conditions and demonstrated increased bacterial contamination of air after turning FAW blankets on; however, this was much lower than worsening of air quality induced by personnel placing a patient in the OR. Tumia et al.[81] undertook air sampling under LAF conditions in orthopedic procedures and failed to identify any significant rise in air bacterial counts with the use of FAW. Sharp et al.[82] also performed air sampling in LAF-equipped ORs to study the effect of FAW on air quality using volunteer patients with psoriasis who had increased shedding of skin cells. Air at 30 cm from a theoretical operating site was sampled and there were no positive cultures. In addition, a smoke test that was used to visually assess airflow found no disturbance by the FAW device. Zink et al.[83] were also concerned by possible contamination of the OR environment with FAW, but did not resort to air sampling. Instead, they placed culture plates on the abdomen of volunteers with use of FAW and failed to identify increased contamination rates with this method.

Albrecht et al. found that the intake filters used in air blowers were not optimally efficient and resulted in colonization of the internal parts of the device. Overall, 92% of the devices they tested resulted in positive bacterial growth with organisms that are typically implicated in PJI (mostly Staphylococci species).[84] However, there is no concrete evidence to link the use of FAW system with SSI/PJI. McGovern et al. studied a change of a warming system from forced air to an alternative system in 1,437 patients. A significant increase in deep joint infection, as demonstrated by an elevated infection odds ratio (3.8, $p = 0.024$), was identified during a period when FAW was used compared to a period when conductive fabric warming was used. The authors conceded that the study was observational and may have been affected by other infection prevention measures instituted by the hospital.[76]

## Question 16: Should OR personnel be required to decontaminate their hands with at least an alcohol-based foam every time their hands have been in contact with inanimate objects (including medical equipment) located in the immediate vicinity of the patient?

**Consensus**
We support current recommendations for hand hygiene in patient care.

**Delegate Vote**
Agree: 86%, Disagree: 8%, Abstain: 6% (Strong Consensus)

**Justification**
Properly performed hand hygiene affords protection to both the patient and healthcare worker from cross transmission of infectious agents. Hand hygiene should be performed by OR personnel involved in examination, manipulation, and placement of the patient, in accordance with the World Health Organization's (WHO) 5 Moments for Hand Hygiene.[85] There is ample evidence to confirm that transmission of pathogens from/to a patient to/from their immediate environment, defined below, occurs. However, there is inadequate evidence to show the influence of hand decontamination on this sequence. High-quality clinical investigations are required to study the efficiency of hand decontamination on prevention of SSI and PJI. Frequent hand decontamination has been suggested,[86] but concerns have been expressed regarding skin irritation and contact dermatitis.[87] Moreover, some risk of change of bacterial flora to colonizing bacteria with skin damage might exist.[88]

Five sequential steps for cross-transmission of microbial pathogens have been described.[86] These steps include shedding of skin flora to inanimate objects surrounding the patients, transfer of the bacteria to the healthcare worker's hands, adequate survival of the microbes on the healthcare worker's hands, inadequate hand antisepsis technique by the healthcare worker, and transmission of bacteria from the healthcare worker's hands to other patients or inanimate objects that can potentially be in contact with patients.

Approximately $10^6$ skin squames containing microorganisms are shed daily from normal skin.[89] Therefore, surfaces located in the close vicinity of the patient (such as floor, bed lines, gowns, furniture, and medical equipment such as blood pressure cuffs) can become contaminated with patients' skin flora.[86,90–92] Hands or gloves of healthcare workers can be contaminated after contact with inanimate objects in patient rooms.[93,94] Laboratory-based studies have demonstrated that many bacteria, including *S. aureus*, Gram-negative bacilli, and *Enterococci*, can be transferred to



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the hands by touching contaminated surfaces.[86,94,95] Microorganisms can survive on hands for different lengths of time varying between a few minutes to several hours and healthcare workers' hands can be progressively colonized due to poor hygiene, longer duration of care, and higher quantity of contamination.[86] In one study, the use of an alcohol gel hand wash was associated with a 36% decrease in nosocomial infection rates.[96] There is substantial evidence that demonstrates improvement in the rate of healthcare-associated infections with hand hygiene promotional programs that include the use of an alcohol-based hand rub, although studies with improved design methodology are needed.[86]

## Question 17: What are the guidelines for hand hygiene and glove use for personnel in contact with the patient for examination, manipulation, and placement on the OR table?

### Consensus

We support current recommendations in patient care in accordance with the principles of Standard Precautions.

### Delegate Vote

Agree: 92%, Disagree: 1%, Abstain: 7% (Strong Consensus)

### Justification

Gloves should be used by OR personnel as dictated by the principles of Standard Precautions.[97] Added protection to the healthcare worker, via glove use, is required in the event of potential contact with blood, body fluids, secretions, excretions, mucous membranes, non-intact skin, or contaminated equipment.[97] Glove use does not preclude the need for application of hand hygiene principles. In the event that the patient is on contact precautions, gloves should be used for all contact with the patient and/or the immediate patient environment. The dynamics of contamination are similar between gloved and ungloved hands.[86] Gloves can be contaminated after touching the patient or inanimate objects in patient rooms.[92,93,98,99] Risk of cross-contamination through contaminated gloves is similar to that of naked hands.[92,99] Therefore, when gloves are used in patient care, hand hygiene must be performed prior to donning gloves and following glove removal. A single pair of gloves may not be used in the care of more than one patient.

## Question 18: Should triple gloving be used to prevent contamination during TJA?

### Consensus

We recommend double gloving and recognize the theoretical advantage of triple gloving.

### Delegate Vote

Agree: 89%, Disagree: 7%, Abstain: 4% (Strong Consensus)

### Justification

A relatively high rate of inner glove contamination has been identified with double-gloving in TJA, leading to the consideration of triple-gloving practices.[100,101] Hester et al.[102] compared the rate of inner glove perforation with three different gloving protocols in TJA: latex/cloth, latex/latex, and latex/cloth/latex. They found a reduced rate of perforation when the outer glove was a cloth glove compared to a latex glove, and interposing a cloth glove between two latex gloves yielded the lowest rate of perforation. While double-gloving with an outer cloth glove had a notable impact on tactile sensation and was troublesome when manipulating cement, triple-gloving with a cloth glove between two latex gloves was not perceived as having such an important impact. However, reported differences in rates were not shown to be statistically significant. Sebold et al.[103] demonstrated that the use of a cloth glove between two latex gloves was able to reduce inner glove perforation rates to zero in their institution. According to their observations, surgeon dexterity was not affected by this gloving practice. In addition, the authors showed that the use of orthopedic outer gloves yielded lower inner glove puncture rates than regular latex gloves. Sutton et al.[104] showed that a triple-gloving protocol with a cut-resistant liner interposed between the two latex gloves significantly reduced the rate of perforation compared to double-gloving with two latex gloves. Overall, triple-gloving seems to decrease inner glove perforation rates; however, this is at the expense of a decrease in surgical dexterity and tactile sensation.

## Question 19: How frequently should gloves be changed during surgery?

### Consensus

We recognize the advantage of glove changes at least every 90 min or more frequently and the necessity of changing perforated gloves. Permeability appears to be compromised by the exposure to methacrylate cement and gloves should be changed after cementation.

### Delegate Vote

Agree: 89%, Disagree: 6%, Abstain: 5% (Strong Consensus)

### Justification

Al-Maiyah et al.[105] conducted an RCT on THA procedures where the study group consisted of changing outer gloves every 20 min and before implant cementation, compared to changing only before cementation in the control group. This change in practice led to a significant reduction in perforation and contamination rates of outer gloves. Kaya et al.[106] reported that glove perforations occurred after 90 min on average and suggested changing gloves every 90 min. Dawson-Bowling et al.[107] evaluated glove contamination after draping and before opening the final components and found 12% and 24% contamination rates respectively.

Beldame et al.[108] identified a significantly higher rate of glove contamination before prosthesis implantation and advised changing gloves before this surgical step. The authors also showed that when the outer gloves were contaminated, changing them lead to noncontaminated outer gloves in 80% of cases. Furthermore, in a prospective study, Carter et al. found that a surgeon's outer glove perforation occurred in 3.7% and 8.3% of primary and revision arthroplasty procedures, respectively. They also found that inner glove perforation was ignored in 19% of double glove perforations and recommended careful inspection of the inner glove whenever outer glove perforation is noted.[100]

## Question 20: When should instrument trays be opened?

### Consensus

We recommend that the timing of opening trays should occur as close to the start of the surgical procedure as possible with the avoidance of any delays between tray opening and the start of surgery.

### Delegate Vote

Agree: 98%, Disagree: 1%, Abstain: 1% (Strong Consensus)

### Justification

Dalstrom et al.[109] recently demonstrated a direct correlation between the duration of open exposure of instrument trays and the risk of bacterial contamination. Some trays were found to be contaminated immediately after opening. After eliminating those trays, they reported contamination rates of 4% at 30 min, 15% at 1 h, 22% at 2 h, 26% at 3 h, and 30% at 4 h. Brown et al.[110] demonstrated that bacterial air counts during preparation and draping were 4.4 times higher than during surgery, leading them to recommend opening instruments after patient preparation and draping.

## Question 21: Should trays be covered with sterile drapes/towels when not in use?

### Consensus

We recognize a theoretical advantage to covering trays when not in use for extended periods, and that larger covers may be disadvantageous, if they are moved from contaminated areas across the sterile field. We recommend further study of this question regarding timing and techniques.

### Delegate Vote

Agree: 90%, Disagree: 4%, Abstain: 6% (Strong Consensus)

### Justification

Chosky et al.[111] demonstrated that covering the instruments with sterile drapes reduced bacterial contamination rates fourfold. The Association of Perioperative Registered Nurses guideline for maintaining a sterile surgical field does not recommend covering the sterile table with sheets that fall below the table top because such a practice may cause air currents that can transfer micro-organisms from a nonsterile area (below the table level) to the sterile field over the table at the time of drape removal[112] Nevertheless, Dalstrom et al.[109] showed that covering trays significantly reduced the risk of contamination and did not identify any increased risk of contamination when uncovering them.

## Question 22: After skin incision, should the knife blade be changed for deeper dissections?

### Consensus

We recognize high contamination rates in studies of scalpel blades that have been used for the skin incision and recommend changes after skin incision.

### Delegate Vote

Agree: 88%, Disagree: 8%, Abstain: 4% (Strong Consensus)

### Justification

In the majority of institutions, separate blades are used for incision of the skin and the deeper tissues during TJA. However, several studies have questioned the necessity of such a practice.[113–115] When comparing contamination of skin and deep knives, Ritter et al.[115] were unable to identify any difference in contamination rates in both conventional and LAF conditions. Furthermore, organisms retrieved from deep wound cultures did not correlate with those that were on the knife blades, thus refuting deep wound contamination by the blades. Other authors subsequently corroborated these findings.[113,114] However, Davis et al.[23] identified a 9.4% contamination rate of superficial blades and supported the routine practice of changing blades after incision. Schindler et al.[116] reported a 15.3% contamination rate for skin blades, 74% of which grew coagulase-negative *Staphylococcus* (CNS), one of the most frequent causes of PJI. In this study, 10.8% of deep blades were contaminated, 50% of which with CNS. Based on their findings, the authors supported changing the skin blade after incision.

## Question 23: Should electrocautery tips be changed during TJA? If so, how often?

### Consensus

In the absence of evidence we recommend further study and no specific behavior.

### Delegate Vote

Agree: 95%, Disagree: 0%, Abstain: 5% (Strong Consensus)

### Justification

After review of the literature, there were no studies relevant to the necessity and frequency of change of electrocautery disposable tips during elective TJA.

## Question 24: Should suction tips be regularly changed during surgery? If so, how frequently? Should suction tips enter the femoral canal?

### Consensus

We recommend changing suction tips every 60 min based on studies showing higher rates of contamination. Suction tips can be introduced into the femoral canal for the time necessary to evacuate fluid but should not be left in the canal, where they circulate large amounts of ambient air and particles that may contaminate the surgery.

### Delegate Vote

Agree: 85%, Disagree: 8%, Abstain: 7% (Strong Consensus)

### Justification

Several studies have demonstrated high rates of contamination of suction tips during the intraoperative period.[23,117–123] In 1988, Strange-Vognsen et al.[123] identified a 54% contamination rate in orthopedic procedures. Twenty years later, Givissis et al.[117] found the same rate of contamination, with 78% of cases growing *Staphylococcus* species. The authors reported one case of deep SSI where the organism was the same as the one isolated from the suction tip. When looking at procedure duration, they showed a 9% contamination rate in procedures lasting less than an hour compared to a 66.7% in procedures lasting over an hour, which led them to advise changing of the catheter tip every hour. Similarly to Strange-Vognsen et al., they recommended turning the suction off when not in use. However, there are concerns that turning off the suction might impose risk of contamination of the surgical field due to backflow of the material along the suction tube and tip.

Greenough et al.[118] found a 37% rate of contamination of operative suctions used in THA. However, when evaluating the suction tips used only for cleaning the femoral shaft, only one of those (out of 31) was contaminated. The authors advised changing the suction tip before preparing the femur in THA. The same conclusion was drawn by Robinson et al.[122] who conducted a similar study among patients undergoing THA in laminar flow rooms and identified a 41% contamination rate of suction tips.

## Question 25: Should splash basins be used, as they are known to be a source of contamination?

### Consensus

We recommend against the use of fluid filled basins that sit open during the surgery.

### Delegate Vote

Agree: 88%, Disagree: 3%, Abstain: 9% (Strong Consensus)

### Justification

Andersson et al.[15] showed that 13 out of 21 irrigation solutions stored in basins were contaminated at the end of the procedure in conventional ventilation rooms. Baird et al. revealed a contamination rate of 74% in their series among specimens taken from splash basin fluids. In their series, *Staphylococcus epidermidis* was the most prevalent organism.[124] Anto et al.[125] demonstrated a 24% rate of contamination of liquid samples removed from the basins. Conversely, Glait et al. recently showed much lower rates of contamination of samples taken from basins that were used to wash and store instruments with only one contaminated case out of 46 (2.17%).[126] However, they used culture swabs as opposed to culturing fluid in other studies.

## Question 26: Do disposable instruments and cutting guides reduce contamination and subsequent PJI?

### Consensus

We recognize the possible theoretical advantages of disposable instrumentation but in the absence of data we can make no recommendations.

### Delegate Vote

Agree: 95%, Disagree: 2%, Abstain: 3% (Strong Consensus)

### Justification

Mont et al.[127] have recently demonstrated a decreased contamination rate of 57% in non-navigated and 32% in navigated cases of TKA when using single-use instruments, cutting blocks, and trials.

Patient specific instrumentation can shorten the duration of surgery in TKA.[128] However, there are no studies that have specifically evaluated the incidence of subsequent PJI in patients that received custom cutting guides or disposable instruments versus those undergoing TJA using conventional instruments and cutting guides. Thus, this issue remains unresolved.

## Question 27: Is there a role for incise draping? What type of incise draping should be used (impregnated or clear)?

### Consensus

We recognize the presence of studies that show iodine-impregnated skin incise drapes decreased skin bacterial counts but that no correlation has been established with SSI. We do not make any recommendations regarding the use of skin barriers but do recommend further study.

### Delegate Vote

Agree: 89%, Disagree: 7%, Abstain: 4% (Strong Consensus)

### Justification

There is concern about the recolonization of skin and surgical site with the host flora during surgery.[129–132]

Incise drapes are intended to provide a sterile barrier at the beginning of the surgical procedure. They are used on prepped surgical sites to provide additional protection and minimize the risk of recolonization. While it has been shown that impregnated incise drapes decrease the recolonization rate of skin flora, there have been inconsistent conclusions about the existing evidence regarding the value of drapes in preventing SSI. High-quality evidence with PJI as an endpoint is lacking. Use of adhesive incise drapes impregnated with iodine should be avoided in patients with systemic or topical allergy to iodine.

The bactericidal action of iodine-containing incise drapes is inferior to conventional skin preparation solutions such as betadine. The sole use of incise drapes as a substitute for conventional skin preparation is not recommended.[133]

In an experimental study on the skin of normal individuals, use of an iodophor-incorporated drape was significantly associated with a lower rate of recolonization of skin bacteria compared with skin-site preparation methods, with or without non-impregnated drape.[131] However, another experimental study on an animal model found that after contamination of skin samples with *S. aureus* suspension, iodine-containing adhesive drapes were as inefficient as the control group in reducing the number of colony-forming units.[134] Another experimental study found that non-impregnated drapes can facilitate the rate of recolonization of skin after antiseptic preparation.[135] In contrast, in an earlier investigation, bacteria did not multiply underneath a plastic adhesive drape and lateral migration of bacteria did not occur.[136]

In a prospective RCT, Chiu et al.[137] could not demonstrate a difference between the wound contamination rates after surgery of acute hip fractures with and without the use of plastic incise drapes (4/65 vs. 1/55 for with and without drapes, respectively).

In another prospective RCT in abdominal surgery, within the group of clean and clean-contaminated procedures, iodophor-impregnated incise drapes significantly reduced the contamination of the surgical wound by normal skin flora organisms, but the study was unable to detect any significant difference in the rate of SSI compared with the control group in whom no drape was utilized (5.9% vs. 5.6% for procedures performed with and without drapes, respectively).[138]

In a prospective study comparing 122 patients undergoing hip surgery in which Ioban (3M Company, USA) was applied to the operative site 24 h before surgery, bacterial sampling of the wound at the end of the procedure showed that the wound contamination rate was reduced from 15% to 1.6% by this method.[139]

One review combined the results of clinical trials of a wide range of clean and clean-contaminated surgical procedures (cesarean sections, abdominal, and hip fracture procedures), most of which did not meet criteria for high quality evidence. In these studies plastic (defined as polyethylene, polyurethane, or polyvinyl) adhesive drapes (e.g., Op-Site (Smith and Nephew), Ioban (3M), Steridrape (3M, United Kingdom)) were utilized. The authors concluded that adhesive drapes are not associated with a reduced infection rate compared with no adhesive drapes and appear to be associated with an increased risk of infection.[140] However, the quality of the few studies included in this systematic review was not high. The authors concluded that if adequately disinfected prior to surgery, the patient's skin is unlikely to be a primary cause of SSI; therefore, attempts to isolate the skin from the wound using an adhesive drape may be pointless and potentially harmful, as excessive moisture under plastic drapes may encourage bacteria residing in hair follicles to migrate to the surface and multiply.[137,140]

Another issue that should be considered is that the type of skin preparation affects drape adhesion.[141] A few studies demonstrated that addition of Duraprep (3M) enhanced the adhesive capacity of drapes.[129,130] Choosing a skin preparation that enhances drape adhesion may minimize drape lifting and the potential for wound contamination. It has been concluded that the separation of incise drapes from the skin was associated with a sixfold increase in the infection rate compared with surgical procedures in which the incise drape was not lifted.[142] A prospective RCT on patients with TJA confirmed that Duraprep solution was associated with significantly better drape adhesion than povidone-iodine scrub and paint. However, the study was not able to demonstrate a significant difference in skin contamination between the groups, although Duraprep was associated with slightly lower rate of contamination.[130]

Allergic reactions to povidone-iodine can occur and there is at least one case report of allergic contact dermatitis associated with the use of iodophor-impregnated incise draping.[143,144]

## Question 28: Does the application of towels or other sterile materials to wound edges and subcutaneous fat during an operation, clipped securely to the edges of the wound, diminish the chances of wound contamination and wound infection?

### Consensus

We recognize the traditional practice of covering skin edges with sterile draping but there is wide variation in clinical practice and we make no recommendations.

### Delegate Vote

Agree: 94%, Disagree: 2%, Abstain: 4% (Strong Consensus)

### Justification

Evidence regarding the application of sterile material to wound edges is mainly available for abdominal open surgery.[145] There is no evidence regarding its use in



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orthopedic surgery and we found no recommendation regarding their use for PJI. Towels can serve to support the drapes against instrument strike-through. They may also protect the wound edges from trauma by instruments such as retractors or broaches.

Wound edge protection devices (wound protectors or wound guards) have been used in abdominal surgery to avoid contamination and trauma of the wound edges during laparotomy.[145,146] There are two main types of protectors: (1) wound protectors with an external and internal ring connected by an impermeable plastic that covers the wound edges and (2) those with an internal ring connected to a drape that extends outward and over the abdomen and is fixed by adhesive material or clips.[146] They provide a physical barrier to protect the incision site from contamination. In contrast, adhesive drapes do not cover the edges of the wound. Wound protectors have only been used in abdominal surgery.[145] Two meta-analyses of RCTs compared the use of wound protectors with no protection in abdominal laparotomy. The authors concluded that their use seems to be protective against SSI.[145,146] However, the quality of those RCTs has been poor. Two multicenter trials on abdominal laparotomy procedures have been registered and are being conducted at the time of writing.[147,148]

## Question 29: What type of draping should be used (reusable or disposable)?

### Consensus
We recognize that penetration of drapes by liquids is believed to be equivalent to contamination and recommend impervious drapes. In the absence of data on disposable versus cloth drapes, we make no recommendation except for further study.

### Delegate Vote
Agree: 90%, Disagree: 6%, Abstain: 4% (Strong Consensus)

### Justification
The available evidence is solely experimental. Most of the studies have been performed in models with rigorous conditions that are unusual in real-life situations. Clinical trials with PJI as an endpoint are lacking.

In addition to the physical properties of material applied for fabricating drapes, factors such as pressure, friction, contact time with contaminated material, state of moisture/dryness, and the moisturizing agent (blood, normal saline, or antiseptic solutions) can affect the bacterial permeability of drapes.[149,150] While passage of bacteria through dry drapes does happen, the strike-through rate of bacteria is enhanced when wetted by normal saline or blood and diminished when wetted by antiseptic solutions (iodine or chlorhexidine).[149] Moreover, drape material may demonstrate different levels of impermeability depending on the penetrating particle (aqueous fluids, albumin, or bacteria).[151–153] Woven and non-woven materials vary in their ability to resist bacterial strikethrough. Disposable nonwoven drapes are superior to reusable woven cotton/linen drapes in resisting bacterial penetration. When wetted by normal saline, reusable woven drapes were penetrated by bacteria within 30 min, while the majority of disposable nonwoven drapes were not.[151] Being impervious does not necessarily mean being absolutely impenetrable to bacteria and impermeability can vary between different disposable drape brands. However, disposable drapes considerably decrease bacterial load passing through them.[154]

Two RCTs were conducted comparing reusable and disposable drapes and gowns in coronary artery bypass graft and elective abdominal surgery, with SSI as their main outcome. None of these studies found differences between the two types of gowns and drapes.[155,156]

## Question 30: Is there evidence that the use of sticky U drapes, applied before and after prepping, effectively seals the non-prepped area from the operative field?

### Consensus
We recognize that adhesive U-drapes to isolate the perineum has been traditional practice but in the absence of data we make no recommendations.

### Delegate Vote
Agree: 83%, Disagree: 11%, Abstain: 6% (Strong Consensus)

### Justification
There are no published or unpublished reports that we could identify that were related to this issue.

## Question 31: Is irrigation useful? How should the delivery method for irrigation fluid be (high pulse, low pulse or bulb)?

### Consensus
We recognize the theoretical basis for irrigation to dilute contamination and non-viable tissue and that a greater volume of irrigation would be expected to achieve greater dilution. We recognize advantages and disadvantages of different methods of delivering fluid but make no recommendations of one method over another.

### Delegate Vote
Agree: 91%, Disagree: 4%, Abstain: 5% (Strong Consensus)

### Justification
There are indirect data regarding the optimal volume of irrigation in TJA. In both animal and human studies, increasing the volume of irrigation solution removes more particulate matter and bacteria, but the effect plateaus depending on the system. There

have been no reported human clinical studies related to the volume of irrigation.[157,158] High-quality studies with PJI as endpoint are lacking. No evidence was found regarding differences in irrigation in primary and revision TJA. Use of high-pressure pulsatile lavage may have potential benefits of being time-saving and removing necrotic tissue and debris more effectively.[159–164] It also improves the mechanical stability of cemented arthroplasty by allowing better cement penetration in cancellous bone tissue. However, there are some concerns regarding damage to tissue structures and propagation of bacteria into the deeper layers of soft tissues with the use of high pressure lavage. High-pressure pulsatile lavage should perhaps be reserved for severely contaminated wounds or for open injuries for which treatment will be delayed. Low-pressure irrigation might be useful if contamination is minimal or treatment is immediate. High-quality evidence is lacking regarding optimum lavage pressure in primary or revision TJA.

Decreases in the amount of bacteria present in the surgical site have been observed with normal saline lavage,[165] indicating that a component of physical removal for every irrigating solution should be considered. For a clean contaminated surgery (appendectomy) irrigation with normal saline was found to decrease SSI in comparison with no irrigation.[166,167] In one study that used pulsatile lavage with normal saline after cemented TKA, particles larger than 1 $\mu$m were collected consecutively after each liter of lavage up to 8 L. The weight of these particles peaked in the first 1 L lavage fluid and gradually decreased until the eighth lavage fluid. Significant differences were found between the first and second, second and third, and third and fourth lavage. However, no significant differences were found beyond the fourth lavage. The results of this study indicated that 4 L of pulse lavage is effective for removing the bone and cement particles during cemented TKA. The authors suggested that if bacteria are considered as particles of approximately more than 1 $\mu$m, 4 L of pulse lavage may be effective for removal of bacterial particles.[158]

The precise definition of high- and low-pressure lavage is not established in the literature. Generally below 15 psi (103.4 kPa) and over 35 psi (241.3 kPa) are considered low or high pressure, respectively.[168] High-pulsatile lavage has been shown to improve cement penetration in cancellous bone and increase mechanical strength at the cement-bone interface during in vitro studies.[169–174] In vivo studies have also demonstrated fewer radiolucency zones in follow up X-rays evaluation.[175] In addition, a relationship between the pressure of irrigation and the quantity of cellular material removed from the bony trabeculae has been demonstrated.[176] However, there is no agreement on a cut-off point for high-pressure lavage. Some studies suggest that even lavage pressures that were considered to be too low to have macroscopic influence may still have an effect on bone marrow mesenchymal cells and direct them to differentiate into adipocyte tissues, thus declining the content of osteoblasts in marrow.[159]

High-pressure lavage may result in tissue damage in cancellous bone, cortical bone, and muscle; and can negatively influence the healing process and early formation of new bone.[91,176–178] Pulsatile lavage (either high or low pressure) results in greater deep bacterial seeding in bone than does brush and bulb-syringe lavage in in vitro models[162,179] and can spread the contamination to nearby tissues.[179] High-pressure pulsatile lavage results in deeper bacterial penetration in muscle tissue in comparison with low-pressure pulsatile lavage.[168]

There is a considerable body of evidence regarding open fractures and contaminated wounds. A few early and recent studies, including in vitro and in vivo human and animal studies, demonstrated that high-pressure pulsatile lavage is more effective than low-pressure pulsatile lavage for removing particulate matter, bacteria, and necrotic tissue, particularly in contaminated wounds that had delayed treatment.[159–164] Moreover, in an experimental model it was demonstrated that low-pressure pulsatile lavage was more effective and efficient than bulb-syringe irrigation in reducing bacterial removal.[180]

One prospective RCT showed that pulsatile lavage in comparison with normal lavage by syringe or jug leads to a lower incidence of PJI after cemented hemiarthroplasty for hip fracture (3/164 vs. 10/192 for pulsatile and syringe lavage groups, respectively).[181]

In another study, the use of high-pressure pulsatile lavage during open debridement for the treatment of acute orthopedic implant infections (mainly TKA, THA, and hip hemiarthroplasty) was associated with a similar success rate compared with the conventional manual low-pressure lavage ($n = 79$).[182]

## Question 32: What type of irrigation solution should be used? Should antibiotics be added to the irrigation solution?

### Consensus

We recognize the mechanical advantage of irrigation as per question 31 but that conflicting evidence exists supporting the use of one agent over the other and make no recommendation regarding type of solution.

### Delegate Vote

Agree: 90%, Disagree: 7%, Abstain: 3% (Strong Consensus)

### Justification

Detergents such as castile soap or benzalkonium chloride are effective in decreasing the burden of bacteria in musculoskeletal wounds because of their surface-active properties. The detergents act by disrupting hydrophobic and electrostatic forces, thereby inhibiting the ability of bacteria to bind to soft tissue

and bone. It is possible that some detergents act on some bacteria more efficiently than on others.[157,183]

Weak evidence is available for the benefit of irrigation with diluted betadine solution before closure of surgical wound. However, no deleterious influence on wound healing or any other major adverse effects have been associated with their use. Concerns for its potential chondrocytotoxicity are supported by experimental evidence only. Lower concentrations (0.35–0.5%) with a short time of lavage might avoid potential chondrocytotoxic effects in partial knee arthroplasty. Further clinical evidence is required to define optimal concentration and length of exposure.

The pharmacodynamic profiles of antibiotics vary depending on the type, dose, and method of delivery.[184] A variation of these factors, a difference in surgical settings in which studies have been performed, and a lack of specific efficacy criteria make it difficult to reach a conclusion regarding whether topical antibiotics are efficacious; and if so, what type should be used and which formulations are optimal for prophylaxis of SSI and PJI. Moreover, the safety of using topical antibiotics has been questioned. Evidence regarding wound irrigation with antibiotic solutions mainly comes from non-orthopedic surgical specialties with clean-contaminated surgeries. Most of these RCTs found that adding antibiotics to irrigation solutions did not decrease the incidence of SSI significantly in comparison with irrigation with normal saline solution.[160,185–189] This finding has also been supported by some experimental studies.[157,190] Further high-level evidence with SSI or PJI as endpoints is required to evaluate the efficacy and potential adverse effects of local irrigation with antibiotic solutions on the surgical site.

In vitro studies show that Castile soap is more effective than antibiotic solutions at removing *S. aureus*, *S. epidermidis*, and *Pseudomonas aeruginosa* from metallic implants and bone.[191,192] In an RCT on open fractures, soap and bacitracin solution did not result in any difference in the incidence of SSI, although bacitracin was associated with more wound complications.[193]

In one RCT in general surgery, there were more wound infections in the saline group (39/258) in comparison with the povidone-iodine solution group (7/242).[194] Irrigation with dilute povidone-iodine solution (0.35%) before closure of the surgical wound in THA and TKA was associated with significant decrease in PJI.[195] The same solution was associated with a significant decrease in deep SSI in spine surgery (6/206 deep SSIs in the no betadine group vs. 0/208 in the betadine group).[196] Ten of 15 studies (11 RCTs and 4 prospective comparative studies) in a systematic review of different surgical specialties (two studies of spine surgery) demonstrated that povidone-iodine irrigation was significantly more effective at preventing SSI than the comparative interventions of saline, water, or no irrigation.[197] The other five studies did not detect any significant difference. This study has considerable methodological limitations, such as considerable variety in the types of surgeries, quality of clean or contaminated interventions, inconsistent concentration of povidone-iodine, and variable use of prophylactic antibiotics. There is no reported complication with the use of dilute betadine irrigation and no adverse effect on wound healing, bone union, or clinical outcome has been reported.[196] One study demonstrated an increased postoperative serum iodine which was not related to any adverse effects.[197] The cytotoxicity of povidone-iodine solution is controversial: Chondrocyte ability for DNA synthesis significantly decreased after 5 min of exposure to povidone-iodine 1%. Other studies similarly show toxic effects of povidone-iodine solution on fibroblasts, keratinocytes, synovial cells and chondrocytes.[198,199] Cytotoxicity has been related in bovine chondrocytes with length of exposure, regardless of concentration, although higher concentrations were associated with less viability of chondrocytes. A concentration of 0.35% povidone-iodine was the least chondrotoxic but still reduced the cell viability when applied for longer than 1 min. Cytotoxicity has been observed in cultured embryonic chicken tibia osteoblasts at a betadine concentration of 5%. Less cytotoxic effect occurs at a povidone-iodine concentration of 0.5%.[200] Povidone-iodine preparations of 1%, 5%, or 10% do not have a deleterious effect on wound healing in animals and humans.[201] Povidone-iodine irrigation should not be used in patients with iodine sensitivity, burns, and thyroid or renal disease.[197] The sterility of povidone-iodine solution before its use should be meticulously monitored because its contamination has been associated with infectious complications.[202,203] One experimental study showed that there was no difference in the quality of cement fixation when irrigation was done with povidone-iodine or normal saline, although both solutions were inferior to hydrogen peroxide solution.[204]

Topical antibiotics should have a broad spectrum and low systemic absorption and be relatively inexpensive and harmless to the tissue. The most commonly used topical antibiotics include cephalosporins, aminoglycosides (neomycin), glycopeptides, chloramphenicol, polymyxin, and bacitracin.[184,205] The potential advantages of topical antibiotic use are their limited potential for systemic absorption and toxicity, low potential for development of antibiotic resistance, and the fact that their effect is essentially independent from the local physiological changes that may affect the efficacy of systemic antibiotics.[206] However, topical antibiotics may produce contact dermatitis or hypersensitivity and their use has been reported to be associated with serious systemic effects such as anaphylaxis with bacitracin and deafness and renal failure with a neomycin–bacitracin–polymixin combination.[207–209] Earlier studies demonstrated that prophylactic topical administration of antibiotics in the surgical incision during various orthopedic and

non-orthopedic procedures is more efficacious than normal saline. However, consistent results have not been reported regarding their efficacy.[165] In vitro and animal studies using bone or metal surfaces failed to show better performance for neomycin and bacitracin solutions in comparison with normal saline for removing bacteria from bone, titanium, and stainless steel.[190–192] Despite evidence that topical antibiotics decrease bacterial inoculum in clean surgical wounds,[210] it has not been shown that they offer any advantage over intravenous antibiotic prophylaxis, nor that they have been proven to decrease the incidence of SSI.[184,186] A study of a canine model for TJA reported a reduction in the SSI rate with neomycin containing irrigation solution.[211] There is concern regarding the adverse effect of topical antibiotic solutions on wound and bone healing. An RCT on open fractures found that topical irrigation with bacitracin solution did not decrease the incidence of SSI in comparison with soap, yet it was associated with a higher rate of wound complications.[193]

## Question 33: Is there a role for intraoperative application of autologous blood-derived products to the wound in preventing infection?

### Consensus

In the absence of data we make no recommendation regarding autologous blood derived products to the wound to prevent infection.

### Delegate Vote

Agree: 94%, Disagree: 2%, Abstain: 4% (Strong Consensus)

### Justification

Although some benefits have been observed regarding the intraoperative application of autologous blood-derived products in TJA, the majority of the studies were not sufficiently powered to be able to detect difference for PJI. Only one RCT demonstrated that use of these products directly decreased the incidence of postoperative wound infection.[212] Larger-scale trials with PJI as an endpoint are required.

In TKA, application of autologous platelet gel and fibrin sealant together on the wound tissues at the end of surgery was associated with a higher postoperative hemoglobin level and decreased the need for blood transfusion. The incidences of wound leakage, wound healing disturbance, and wound infection (0/85 vs. 4/80) were significantly less in patients managed with platelet gel and fibrin sealant.[212]

In a multi-center study ($n = 58$) topical spraying of fibrin tissue adhesive (non-autologous cryoprecipitate-based fibrinogen) was added to standard hemostatic measures in TKA and resulted in a decrease in blood loss and reduced blood transfusion requirements. There were three cases of superficial wound infection (2/29 and 1/29 for the treatment and control groups, respectively) without any significant difference.[213] Other similar RCTs on TKA ($n = 53$)[214] and THA ($n = 81$)[215] reported similar findings regarding blood loss.

In one RCT using autologous fibrin sealant in THA, there was an association with less wound drainage and blood loss (no significant difference), yet the transfusion rate and hospital stay remained similar to the control group.[216]

One review included six trials[213–218] that studied the use of fibrin sealants in orthopedic surgery. In these trials 482 patients were included, of whom 235 were randomized to receive fibrin sealants. The review found use of fibrin sealant in the context of orthopedic surgery that was associated with a reduced postoperative blood loss on average around 223 ml per patient, and reduced the risk of exposure to allogeneic red blood cell transfusion by 32%. Fibrin sealant treatment was not associated with an increased risk of wound infection, any infection, hematoma formation, or death. Hospital length of stay was not reduced in patients treated with fibrin sealant.[219]

## Question 34: Do staples or the type of suture have an effect on infectious events? If so, what is the best closure method to prevent infectious events?

### Consensus

In the absence of conclusive data and the wide variability in surgical practice, we make no recommendation regarding specific sutures or staples to prevent infection.

### Delegate Vote

Agree: 92%, Disagree: 3%, Abstain: 5% (Strong Consensus)

### Justification

We are unable to draw a clear conclusion about the best method for closure to prevent infectious complications due to inadequate definitions for infection complications of surgical wounds. In addition, the majority of the studies reviewed were underpowered. Evidence is lacking regarding patients whose health may interfere with wound healing and in surgical sites of high tension. Tissue adhesives should be considered as a biological sealant rather than a closure method of mechanical strength.

In an RCT that included 90 patients who underwent TKA, no significant differences in infection, dehiscence, general health, and functional and clinical assessments were observed. The study compared the following: (1) combined suture tissue adhesives defined by sutures for capsule and subcutaneous layers and tissue adhesive (2-octyl or $n$-butyl-2) for the final cutaneous layer, (2) staples, and (3) conventional subcuticular suture approach (sutures used for the capsule, subcutaneous, and cutaneous layers). It was

observed that the length of hospital stay was higher with the staple group.[220]

Another trial included 187 patients who underwent TKA ($n = 85$) and THA ($n = 102$) and compared wound closure with 2-octylcyanoacrylate (OCA), staples, and sutures.[221] Early wound discharge (less than 24 h postoperatively) was reduced with OCA in both THA and TKA. In TKA, prolonged wound discharge was observed with OCA. No significant difference was observed in the incidence of superficial wound infections between groups. No deep infection was detected. Sealing of the wound as measured by blood strike-through onto the dressing was significantly improved with OCA in both joints. The authors concluded that for more mobile surgical wounds (such as with TKA), OCA might not be appropriate for skin closure because it does not provide adequate resistance for withstanding early rehabilitation.

In another trial including 90 patients with THA, skin adhesive and surgical staples were both effective skin closure methods. Staples were quicker and easier to use than skin adhesive and less expensive. No significant difference was found regarding the occurrence of complications, although the study was not adequately powered to detect any case of deep infection.[222]

A review of RCTs in a wide range of non-orthopedic surgical specialties with pediatric and adult patients[223] concluded that sutures were significantly better than tissue adhesives for minimizing dehiscence. Sutures were also found to be significantly faster to use. No differences were found between tissue adhesives and tapes for minimizing dehiscence or infection. Tapes and staples were significantly faster to use than tissue adhesives. For all outcomes of dehiscence and infection there were no statistically significant differences between high- and low-viscosity adhesives.

Smith et al.[224] performed a meta-analysis to compare the clinical outcomes of the use of staples and sutures in orthopedic surgery. The authors included six small-sized studies and noted major methodological drawbacks including inadequate definitions for superficial and deep infections in most of them. Based on these studies, they found a significantly higher risk of developing wound infection when the wound was closed with staples rather than sutures (17/350 vs. 3/333 superficial or deep infections for staples and sutures, respectively). Five of the six studies included data on patients who underwent hip surgery. A higher risk of infection with staples also existed in patients who underwent hip surgery. At this point there is need for future studies to evaluate this issue further.

## Question 35: Does the use of a surgical safety checklist and time-out affect the rate of SSI in arthroplasty patients?

### Consensus

We support the surgical checklist protocol as beneficial to patient safety, and specifically as it applies to correct administration of prophylactic antibiotics.

### Delegate Vote

Agree: 97%, Disagree: 1%, Abstain: 2% (Strong Consensus)

### Justification

Checklists seem to improve inter-professional communication in the OR. High-quality evidence exists supporting the beneficial effect of surgical safety checklists and time-outs for reduction of SSI and other major postoperative complications by assuring timely administration of preoperative antibiotic prophylaxis. However, evidence shows that many elements of adapted checklists are not adequately performed. There is no evidence regarding the influence of implementing a mandatory surgical checklist on appropriate application of evidence-based measures for SSI in TJA. Existing evidence shows the beneficial effect of mandatory safety checklists on infectious complications for other simpler procedures.

One study showed that implementation of an inter-professional preoperative checklist in the OR was associated with a decline in communication failures (mean number of communication failures per procedure decreased from 3.95 to 1.31; the number of communication failures associated with visible negative consequences decreased by 64%).[225]

A relationship appears to exist between the adoption of a routine preoperative checklist by the surgical team and improvement in the timing of antibiotic prophylaxis.[226–228] In a prospective study of eight diverse hospitals around the world (including high- and low-income locations), substantial decreases in major surgical complications and mortality during the early postoperative period was observed after implementation of a World Health Organization checklist in the OR. The adherence rate to appropriate preoperative antibiotic administration increased from 5% to 83% and the incidence of SSI significantly decreased from 6.2% to 3.4% ($p < 0.001$). The improvement in quality of care was observed even with incomplete compliance of the checklist.[229] In another study performed in hospitals with a high standard of care in the Netherlands, performing the surgical patient safety system checklist, which includes pre-, intra-, and postoperative elements, also reduced the incidence of SSI (from 3.8% to 2.7%, $p = 0.006$) as well as other major postoperative complications. Compliance was associated with greater improvements in quality of care.[226]

In a prospective study, it was observed that many evidence-based measures for SSI reduction (prophylactic antibiotic timing, maintaining normothermia during surgery, appropriate urinary tract catheterization, and hand hygiene) were not applied adequately for arthroplasty procedures and the situation was even worse for fracture surgeries.[230] There is no evidence regarding the influence of a mandatory checklist on appropriate application of its components. However, there are prospective studies demonstrating that

implementing mandatory checklists resulted in decrease in the incidence of central line associated bloodstream infections in intensive care unit patients.[231,232]

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